UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,872	03/24/2004	Mian Ying Wang	10209.476	6611

21999 7590 03/23/2009

KIRTON AND MCCONKIE
60 EAST SOUTH TEMPLE,
SUITE 1800
SALT LAKE CITY, UT 84111

EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
03/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,872	WANG ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *12/23/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/17/08 has been entered.

Claims 1-13 are pending in the application.

It is noted that *Morinda citrifolia* may be referred to herein as 'MC' or 'noni.'

Claims 12-13 remain withdrawn from examination on the merits, being elected without traverse because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement of 4/6/06.

Claims 1-11 were examined on their merits with regard to the elected species of *Morinda citrifolia* leaf extract. It is noted that in the most recent amendment submitted

by Applicants on 12/23/2008, Applicants have amended claim 1 to specifically recite '*Morinda citrifolia* liquid leaf extract.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended claims 1 and 7 to require that the MC leaf extract is a 'liquid' extract. This phrase is very broad and can mean that the extract has been submerged in a liquid, or alternatively, that the MC leaf is extracted by a liquid. The term 'liquid' is quite broad and is much broader than a 'solvent.' The disclosure as filed

does not teach wherein MC leaf is extracted by a representative number of solvents, and additionally, by a representative number of 'liquids' as the claims newly recite. Hence, the scope of what Applicant is now claiming by reciting *'Morinda citrifolia* liquid leaf extract' is of a much broader scope than originally disclosed by Applicants and is therefore considered New Matter.

Applicant is asked to either remove the New Matter from the claims, amend the claims accordingly or to provide the Examiner indication of where to find this information in the specification (either implicitly or explicitly) in order to overcome this rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 and 9-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No.11/668,035 ('035). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '035 'make obvious' claims 1-11 in this application for the following reasons:

Claims 1-16 of '035 are directed toward a method for inhibiting Aromatase and Aromatase enzymes that function to convert androgens to estrogens comprising administration of an MC product (which can be MC dietary fiber – see claim 5 of '035) between about 0.01 and 100%, quercetin between about 0.1 and 10%, rutin between 0.1 and 10%. The claims of '035 do not specifically teach the ingestion administration as Instantly claimed (claims 3 and 10).

It is noted that claim 1 broadly recites an MC leaf extract. Limitations from the specification are not read into the claims. Absent any clear definition of MC leaf extract, this product is given its broadest interpretation within reason. It is deemed that an MC leaf extract can be directed toward MC dietary fiber, because dietary fiber (cellulose for example) can be extracted from MC leaf. Thus, claim 2 adding additional dietary fiber would amount to the same, yet in an added amount, of MC leaf extract (being the dietary fiber). Clearly, a method for inhibiting Aromatase and Aromatase enzymes that

function to convert androgens to estrogens makes obvious a method for selectively inhibiting estrogen production and providing estrogenic effects in that, plainly stated by the preamble of claim 1 of '035 states that inhibition of aromatase enzymes will inhibit estrogen production (selectively, by enzyme inhibition); inhibition of estrogen production would necessarily provide estrogenic effects.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

Claims 1-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly (US 6,340, 703) in view of Chang et al. (US 2006/00996900 A1) in view of Davis (US 5,708,038) in view of Elkins, R. (1998) in view of Flockhart et al. (WO 9307901 A1) in view of Wang et al. (2002).

Whereby Applicants have amended claims 1 and 7 to state that the MC extract is a 'liquid' extract does not render the claims patentable. The phrase 'liquid extract' merely tends to state that water must be present which would be a consequence, for example, of combining MC juice with beta-sitosterol. Further, while the phrase may also be interpreted to mean that the MC leaf has been extracted with a liquid, the entire

phrase states '*processed Morinda citrifolia* liquid leaf extract' (emphasis added) which is still broadly directed toward any single compound present in a *Morinda citrifolia* leaf which is *extractable* from the leaf with a liquid. Hence, the extract still reads on beta-sitosterol.

Kelly taught that quercetin was a flavonoid known to be estrogenic (see col. 3, lines 21-38).

Kelly did not teach the incorporation of rutin or a leaf extract of MC or MC juice or wherein the MC leaf extract was present in a dermal composition or the particular dosage regimens/amounts of constituents as Instantly claimed.

Chang et al. (US 2006/00996900 A1) taught that rutin was a compound known to bind to the estrogen receptor (see [0068]).

Davis (US 5,708,038) taught that beta-sitosterol possesses estrogenic activity (col. 3, lines 8-20).

Elkins, R. (1998) teaches that MC leaf contains beta-sitosterol (see p. 8).

Flockhart et al. (WO 9307901 A1) taught methods for the systemic transdermal delivery of medicinally active plant extracts (see for example, page 1, last three paragraphs, page 4, last two paragraphs and page 6, last paragraph).
Wang et al. (2002) reported many traditional uses of MC plants (see entire reference, especially pages 1-3). Wang et al. explained that MC juice had been used to treat menstrual difficulties (see specifically, page 2, last paragraph), and further disclosed that MC fruit contained rutin (see specifically, p. 3, fourth full paragraph).

Wang et al. (2002) reported many traditional uses of MC plants (see entire reference, especially pages 1-3). Wang et al. explained that MC juice had been used to treat menstrual difficulties (see specifically, page 2, last paragraph), and further disclosed that MC fruit contained rutin (see specifically, p. 3, fourth full paragraph).

Thus, MC juice is another compound in Applicants claimed list of ingredients which comprises estrogenic compounds and was known to cause estrogenic effects (treatment of menstrual difficulties). As keenly pointed out in previous Office actions, combining ingredients which were all known to be estrogenic (or which have been recognized as containing estrogenic ingredients) is obvious. "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301. The ordinary artisan would have had a reasonable expectation that

the combination of claimed elements would result in a composition with additive estrogenic effects.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating inflammation of mucous membranes. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943). Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

One of ordinary skill in the art would have been motivated to combine rutin and quercetin as well as an MC leaf extract containing beta-sitosterol for inhibiting estrogen production and providing estrogenic effects because quercetin and beta-sitosterol were known estrogenic agents, and rutin was known to bind to the estrogen binding site. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention based upon the combination of the references.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components as well as dosage regimens of the claimed components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. Further, if there are any differences between Applicant's claimed method and that suggested by the combined teaching of the prior art, the differences would be appear minor in nature.

Further, although the prior art does not specifically state to take the formulation 'before a meal', it is deemed that there is no specific time-limit set forth in the claims. Therefore, the MC leaf extract of the prior art must have been taken before a meal, even if it was minutes, hours or days prior to a meal.

Claims which state using the dietary supplement as an 'aromatase inhibitor' or 'to provide estrogenic effects in the body' does not functionally change the method of the claimed invention. It is deemed that the because the product of the prior art and the product of the claims are the same, that the composition would have inherently performed these characteristics and are therefore anticipated by the prior art.

Although the prior art did not specifically teach wherein the MC leaf extract was present in a dermal composition, formulating active ingredients into varying delivery vehicles was routine in the art at the time the invention was made as indicated by Flockhart et al.. Transdermal delivery is well known in the art as a means for transporting active agents across the dermal layers and into the bloodstream. Therefore, the mere addition of a known, medicinally active ingredient into a topical formulation is considered obvious.

Further, it has been held that:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable varition..103 likely bars its patentability…if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Applicants' arguments pertaining to this rejection were carefully considered, however, not found persuasive.

Initially, Applicants reiterate the Graham factual inquiries and reassert the 103(a) statute (pp. 5-6, Remarks). Applicants contend that the Examiner has not set forth a

prima facie case of obviousness under the 103(a) statute in light of the Graham factual inquiries because Applicants assert that the cited prior art of record does not teach every limitation in the claimed invention (p. 6, Remarks). Applicants assert that "...a rejection under Section 103 cannot stand it if contains a mere statement that the claimed invention would have been obvious without explicitly enumerating the necessary factual findings.

The Examiner has set forth a clear case of obviousness in this and prior Office actions. The Examiner has not simply indicated that it would have been obvious to combine the Instantly claimed ingredients; but rather, provided a keen rational for why the ordinary artisan would have found that combining the Instantly claimed ingredients would be useful. Specifically, all of the claimed ingredients were either known estrogenic compounds, or ingredients known to contain estrogenic compounds. Combining ingredients based upon their known, similar functions is obvious (*In re Kerkohoven*).

Applicants argue:

> However, the claimed invention involves ranges, which produce unexpected results. In particular the process for utilizing a leaf at higher concentrations administration of Morinda citrifolia leaf extract according to the claims of the present invention have produced unexpected estrogenic affects, when viewed against the background of prior art which teaches that administration of whole foodstuffs containing isoflavones have shown no consistent effect and that plant sterols have been estimated to be approximately 1/400 of that recorded for estradiol. (pp. 6-7, Remarks).

While Applicants' arguments in contention of an unexpected result was carefully considered, such contentions are deemed mere allegations absent any side-by-side comparison with beta-sitosterol, a compound already known in the art to be inherent in MC leaf and additionally known to possess estrogenic activity as disclosed by Elkins and Davis. Absent such verifiable proof, Applicant's assertions are unsubstantiated. It is additionally pointed out that in the event that Applicants do convincingly verify an unexpected result, the claims must be commensurate in scope with such results.

Applicants further contend that the claimed ranges of MC provide for an unexpected result, which obviates this outstanding rejection: "...administration of a leaf extract according to the claims of the present invention produced an estrogenic effect nearly ½ as potent as that as shown by estradiol. Accordingly, the inventive processing methods utilized, and administration of the claimed invention, have produced unexpected estrogenic effects when taken in view of the prior art" (p. 7, Remarks). Applicant has not explained how this data is unexpected. One would expect that MC leaf extract would have estrogenic effects based upon the fact that it contains at least the flavonoid glycoside known to be estrogenic. Further, it appears that Applicants are reading limitations which are not present in the claims. The claim is directed broadly toward '*Morinda citrifolia* leaf extract'. A *Morinda citrifolia* leaf extract is broad enough to read on beta-sitosterol, alone. To reiterate from previous Office actions, Elkins, R. (1998) disclosed that MC leaf contains beta-sitosterol (p. 8 of Elkins). Applicants have not defined the phrase *'Morinda citrifolia* leaf extract' in the Specification, and although

Applicants use a specific type of extract, these limitations are not read into the claims. Considering that plant extracts are known to be in the forms of crude extracts, partially purified extracts and purified extracts containing one compound, coupled with the fact that MC leaf contains beta-sitosterol offers that the breadth of the claim may mean that a "*Morinda citrifolia* leaf extract' *is* beta-sitosterol. The term 'extract' is simply a product-by-process. The patentability of this type of product is centered around the product, and not the method for making. Thus, because beta-sitosterol is *extractable* from MC leaf, the interpretation of the breadth of *'Morinda citrifolia* leaf extract' as being beta-sitosterol is not unreasonable.

Applicants argue that Kelly state "'….[c]linical and other studies done to date in this area are highly equivocal…..other biologically active components'…Kelly indicates that producing a consistent estrogenic effect by administration of isolated biologically active compounds was beyond the reach of one skilled in the art, and that the interplay between various compounds was sufficiently complicated so as to obfuscate from one skilled in the art which combinations of compounds would effectively act to produce the desired estrogenic effects..." (p. 7, Remarks). However, reading on, Kelly states "Even when a positive clinical effect has been obtained, it has been with a mixture of a plurality of isoflavones, as well as a wide range of other unidentified dietary components and other biologically active components – it is known for example that other compounds present in legumes such as flavonoids (e.g. quercetin, luteolin, kaempferol and lignans) also are estrogenic and it is also likely that among the other 700 or so isoflavonoids present in the Leguminosae family there are as yet unidentified

isoflavonoids with estrogenic activity" (Col. 3, lines 31-38). Hence, it appears that Applicants have misinterpreted the teachings of Kelly because Applicants' arguments are respectfully out of context with the actual teachings of Kelly. Kelly is teaching that estrogenic effects of natural materials is unpredictable (as recited in the passage cited by Applicants); however, ***Kelly specifically points out that flavonoids such as quercetin are known estrogenic compounds***. Hence, Applicants' arguments are not found convincing.

Applicants argue that Kelly does not disclose the amount of quercetin as Instantly claimed. As stated in previous Office actions, quercetin was a known effective variable as quercetin was a known estrogenic compound. Where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Adjusting the amounts of quercetin as Instantly claimed is deemed routine optimization of a result effective variable and it not deemed inventive absent evidence of an unexpected result.

Applicants argue that "Chang discloses only that rutin is a flavonoid glycoside comprised of quercetin and a sugar, rutinose, and that many beneficial heath effects of rutin have been demonstrated. Chang fails to disclose the claimed ranges of rutin and quercetin, and fails to teach the unexpected result that higher concentrations cause an inhibition of enzyme induction…Chang's disclosure certainly does not provide insight

that would have allowed one skilled in the art to solve the problem posed by Kelly, that administration of biologically active components had failed to produced [*sic*] consistent desirable estrogenic effects (p. 8, Remarks).

First, Applicants' rational including Kelly is respectfully found to be without merit because Applicants have mischaracterized the teachings of Kelly as indicated *supra*. While Chang does not disclose the amounts of rutin and quercetin as Instantly claimed, it was keenly established in the previous Office action that the routine adjustment of amounts of known, effective ingredients to incorporate into neutraceutical/pharmaceutical preparations was considered *prima facie* obvious to the ordinary artisan at the time the invention was made. Applicant's argument that Chang fails to teach "...the unexpected result that higher concentrations cause an inhibition of enzyme induction" is unsubstantiated " because first, Applicants have not shown that higher amounts of rutin or quercetin have an unexpected result over the rutin and quercetin of the prior art. Applicants' arguments in contention of an unexpected result on page 6 of the remarks are associated with *Morinda citrifolia* leaf extract, and not with amounts of quercetin or rutin which may provide for an unexpected result. Thus, there is no evidence of record to indicate that the claimed ranges of quercetin or rutin provide for any unexpected estrogenic activity. Also, it is reminded that A rejection under 35 U.S.C. ' 103 based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention. Ex parte Raychem Corp, 17

U.S.P.Q. 2d 1417. Thus, with regard to Applicants' contentions presented *supra*, as well as Applicants' arguments presented on p. 8 ('The magnitude of the unexpected result, as indicated in the table on p. 23....), the ordinary artisan at the time the invention was made, with the aforementioned references before him/her would have been motivated to combine the Instantly claimed ingredients because they were all known to have estrogenic effects. Thus, the ordinary artisan would have had a reasonable, predictable degree of success in producing the claimed invention; and further, with the prior knowledge that both quercetin and rutin were estrogenic, the adjustment of concentrations of each of rutin and quercetin in neutraceutical/pharmaceutical preparations would have been well within the purview of the ordinary artisan at the time the invention was made.. "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton *KSR* 127S. Ct. at 1742. Additionally, the evidence presented on p. 23 of the Specification does not exemplify a result which would be 'unexpected' as alleged by Applicants as there is no data verifying that these results are indeed 'unexpected.'

Applicants argue:

> Kelly's concern with equivocal results is compounded by Davis' assertion, that even when effective, plant sterols produce only a mild estrogenic effect. Davis discloses that estrogens have been isolated from a number of plant sources and that to date, only three sterols having mild estrogenic activity have been isolated. Importantly, Davis teaches that the estrogenic activity of plant sterols has been estimated to be approximately 1/400 of that recorded for estrodile. Accordingly, not only does Davis fail to disclose the claimed ranges of quercetin and rutin, and the unexpected result that higher concentrations cause inhibition of enzyme induction, but Davis additionally teaches away from the use of plant sterols in favor of estrodile, as the plants produce only a mild estrogenic effect, approximately 1/400 of that recorded for estrodile (p. 8, Remarks).

Again, Applicants' assertions concerning Kelly have respectfully been taken out of context. Furthermore, Applicants' arguments concerning Davis tend to be tangential to the teachings of Davis who specifically teaches that beta sitosterol possesses estrogenic activity. Again, Applicants' arguments pertaining to 'higher concentrations' only pertain to the amount of Morinda citrifolia leaf extract as disclosed in the specification, the specific extract not being explicitly claimed.

Therefore, while Davis discloses the advantageous use of estradiol over other plant sterols, it is clear that 'estradiol' is 'beta-estradiol', the same compound found in MC leaf. Further, as Applicants state, Davis does not specifically teach rutin or quercetin or any other specific plant sterols. Thus, Davis does not 'teach away' from the use of other plant sterols such as rutin or quercetin in any pharmaceutical preparation or their own preparation as asserted by Applicants on pp. 7-8 of the Remarks. On the contrary; Davis is merely reporting the advantageous effects of beta-sitosterol which is not deemed to negate any positive estrogenic effects innately possessed by quercetin or rutin which were already known in the art:

> **Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments**. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition **does not become patentable simply because it has been described as somewhat inferior to some other product for the same use**." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (See, MPEP § 2123, emphasis added)

Thus, Applicants' arguments pertaining to Davis 'teaching away' from the claimed invention are not accepted.

Further, with regard to the arguments pertaining to Davis, Applicant is again imparting piecemeal analysis to the references; while the rejection is made in view of the combination of the references. It is reiderated that an unexpected result has not been established as Applicants contend.

> [If]… there are [a] finite number of identified, predictable solutions, [a] person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007.From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

/Patricia Leith/
Primary Examiner, Art Unit 1655